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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,527	10/19/2001	Raymond A. Dwek	2543-1-023	1260

7590 07/16/2002

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EXAMINER	
PAPPU, SITA S	

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,527	Applicant(s) DWEK ET AL.	
	Examiner S. Pappu	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-38 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 9-11, 14, 15, 25-28, 33-35, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is an imidosugar and the agent is an enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

II. Claims 1-4, 9, 12, 14, 15, 25-28, 33, 36, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is an imidosugar and the agent is a molecule which increases the activity of the enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

III. Claims 1-4, 9-11, 13-15, 25-28, 33-35, 37, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is an imidosugar and the agent is a nucleic acid sequence which encodes a neuronal glycolipid degrading enzyme, classified in class 514, subclass 44.

IV. Claims 1, 5, 9-11, 14, 15, 25, 29, 33-35, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is PDMP or TPDMP, and the agent is an enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

V. Claims 1, 5, 9, 12, 14, 15, 25, 29, 33, 36, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is PDMP or TPDMP and the agent is a molecule which increases the activity of the enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

VI. Claims 1, 5, 9-11, 13-15, 25, 29, 33-35, 37, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is PDMP or TPDMP and the agent is a nucleic acid sequence which encodes a neuronal glycolipid degrading enzyme, classified in class 514, subclass 44.

VII. Claims 1, 6, 9-11, 14, 15, 25, 30, 33-35, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is a nucleic acid encoding a

protein capable of inhibiting glycolipid synthesis, and the agent is an enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

VIII. Claims 1, 6, 9, 12, 14, 15, 25, 30, 33, 36, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is a nucleic acid encoding a protein capable of inhibiting glycolipid synthesis and the agent is a molecule which increases the activity of the enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

IX. Claims 1, 6, 9-11, 13-15, 25, 30, 33-35, 37, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is a nucleic acid encoding a protein capable of inhibiting glycolipid synthesis and the agent is a nucleic acid sequence which encodes a neuronal glycolipid degrading enzyme, classified in class 514, subclass 44.

X. Claims 1, 7, 9-11, 14, 15, 25, 31, 33-35, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is an antisense nucleic acid

sequence, and the agent is an enzyme involved in glycolipid degradation,, classified in class 514, subclass 2+.

XI. Claims 1, 7, 9, 12, 14, 15, 25, 31, 33, 36, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is an antisense nucleic acid sequence and the agent is a molecule which increases the activity of the enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

XII. Claims 1, 7, 9-11, 13-15, 25, 31, 33-35, 37, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is an antisense nucleic acid sequence and the agent is a nucleic acid sequence which encodes a neuronal glycolipid degrading enzyme, classified in class 514, subclass 44.

XIII. Claims 1, 8, 9-11, 14, 15, 25, 32, 33-35, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is a catalytic RNA sequence, and the agent is an enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

XIV. Claims 1, 8, 9, 12, 14, 15, 25, 32, 33, 36, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is the inhibitor is a catalytic RNA sequence and the agent is a molecule which increases the activity of the enzyme involved in glycolipid degradation, classified in class 514, subclass 2+.

XV. Claims 1, 8, 9-11, 13-15, 25, 32, 33-35, 37, 38, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation wherein the inhibitor is a catalytic RNA sequence and the agent is a nucleic acid sequence which encodes a neuronal glycolipid degrading enzyme, classified in class 514, subclass 44.

XVI. Claims 16-19, 24, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis in combination with bone marrow transplantation, wherein the inhibitor is an imidosugar, classified in class 514, subclass 44.

XVII. Claims 16, 20, 24, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis in combination with bone marrow transplantation, wherein the inhibitor is PDMP or TPDMP, classified in class 514, subclass 2+.

XVIII. Claims 16, 21, 24, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis in combination with bone marrow transplantation, wherein the inhibitor is a nucleic acid encoding a protein capable of inhibiting glycolipid synthesis, classified in class 514, subclass 44.

XIX. Claims 16, 22, 24, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis in combination with bone marrow transplantation, wherein the inhibitor is an antisense sequence, classified in class 514, subclass 44.

XX. Claims 16, 23, 24, drawn to a method for treating a glycolipid storage-related disorder by administering an inhibitor of glycolipid synthesis in combination with bone marrow transplantation, wherein the inhibitor is a catalytic RNA sequence, classified in class 514, subclass 44.

Claims 1, 9, 14, 15, 25, 33, 38 embrace the inventions of Groups I-XV. Should one of these Groups be elected, claims 1, 9, 14, 15, 25, 33, 38 will be examined only to the extent they encompass the elected subject matter.

Claims 10, 11, 34, 35 embrace the inventions of Groups I, III, IV, VI, VII, IX, X, XII, XIII, XV. Should one of these Groups be elected, claims 10, 11, 34, 35 will be examined only to the extent they encompass the elected subject matter.

Claims 2-4, 26-28, embrace the inventions of Groups I-III. Should one of these Groups be elected, claims 2-4, 26-28 will be examined only to the extent they encompass the elected subject matter.

Claims 5, 29 embrace the inventions of Groups IV-VI. Should one of these Groups be elected, claims 5, 29 will be examined only to the extent they encompass the elected subject matter.

Claims 6, 30 embrace the inventions of Groups VII-IX. Should one of these Groups be elected, claims 6, 30 will be examined only to the extent they encompass the elected subject matter.

Claims 7, 31 embrace the inventions of Groups X-XII. Should one of these Groups be elected, claims 7, 31 will be examined only to the extent they encompass the elected subject matter.

Claims 8, 32 embrace the inventions of Groups XIII-XV. Should one of these Groups be elected, claims 8, 32 will be examined only to the extent they encompass the elected subject matter.

Claims 12, 36 embrace the inventions of Groups II, V, VIII, XI, XIV. Should one of these Groups be elected, claims 12, 36 will be examined only to the extent they encompass the elected subject matter.

Claims 13, 37 embrace the inventions of Groups III, VI, IX, XII, XV. Should one of these Groups be elected, claims 13 and 37 will be examined only to the extent they encompass the elected subject matter.

Claims 16 and 24 embrace the inventions of Groups XVI-XX. Should one of these Groups be elected, claims 16 and 24 will be examined only to the extent they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Groups I-XV are directed to a method of treating a glycolipid storage-related disorder by administering different combinations of inhibitors and agents and are therefore involve different method steps, modes of action and effects and are thus distinct.

Groups XVI-XX are directed to a method of treating a glycolipid storage-related disorder by administering different combinations of inhibitors in combination with bone marrow transplantation and do not involve the administration of any agent and are thus distinct from Groups I-XV. Groups XVI-XX are distinct from each other because they involve different inhibitors.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, the search required for one Group is not required for other Groups, restriction for examination purposes as indicated is proper.

Claims 14, and 38 are generic to a plurality of disclosed patentably distinct species comprising Gaucher disease, Sandhoff's disease, Fabry's disease, Tay-Sach's disease, Niemann-Pick disease, GM1 gangliosidosis, Alzheimer's disease, stroke, epilepsy. These diseases have different etiologies, symptomatologies and animals that are models of each of these diseases will have different phenotypes and exhibit different responses to the treatment methods claimed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER

S. Pappu
July 2, 2002